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TITLE: DEVICE FOR SEPARATING THE EPITHELIUM LAYER FROM THE SURFACE OF THE CORNEA OF AN EYE

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DEVICE FOR SEPARATING THE EPITHELIUM LAYER FROM THE SURFACE OF THE CORNEA OF AN EYE

BACKGROUND

LASIK (Laser-Assisted *In Situ* Keratomileusis) is a surgical procedure intended to reduce a person's dependency on glasses or contact lenses. LASIK permanently changes the shape of the cornea, the clear covering of the front of the eye, using an excimer laser. A device, called a *microkeratome*, is used to cut a flap in the cornea. A hinge is left at one end of this flap. The flap is folded back revealing the stroma, the middlesection of the cornea. Pulses from a computer-controlled laser vaporize a portion of the stroma and the flap is replaced. It is important that the knife used during the LASIK procedure is sharp, otherwise the quality of the procedure and the healing time are poor. Additionally the knife has to be sharp in order to produce consistent and reproducible flaps. There are some complications related to the use of microkeratomes. The most common complication is the creation of an irregular flap, for example, a half flap, buttonhole, or total cup. These complications represent irregular incisions of the cornea, a situation that can permanently degrade visual performance.

Before LASIK, PRK (Photo-Refractive Keratectomy) was used to correct the curvature of the cornea. A physician could scrape away a superficial layer, e.g., the epithelium, of the cornea. After the superficial layer was removed, laser treatment was applied on to the exposed surface of the cornea. A problem existed, however, in that the healing period for the eye typically lasted for a week, much longer than the healing period of LASIK. Also, the patient experienced a lot of pain during healing. Typically in PRK a disposable contact lens is used to cover the treated area of the cornea and help reduce postoperative pain.

In another technique, LASEK (Laser Epithelial Keratomileusis) the epithelial layer is separated from the surface of the cornea in a manner that the separated epithelial layer can be preserved. First, the epithelium is treated with and alcohol solution to partially devitalize it. Once the exact

surface area of treatment is determined, a few drops of a weak alcohol solution is applied to the surface of the cornea and allowed to stay in contact with the epithelium for a few seconds. This weak alcohol solution is then rinsed off the surface of the eye. The function of the weak alcohol solution is to loosen the epithelial layer (50 microns) and to allow it to be peeled back in a sheet of epithelial cells, thereby exposing the underlying cornea. This is not to be confused with LASIK, which actually uses a microkeratome instrument to create a flap of both epithelium and the front part of the stromal tissue measuring anywhere between 130 to 180 microns.

In LASEK, the epithelium-only layer is laid back in a similar fashion to LASIK, but consists of only epithelium, not corneal stroma. Once the epithelial cells have been laid out of the way, the laser is applied to the surface of the cornea in the exact same fashion as in PRK. Once the laser treatment has been completed, the epithelial layer is laid back into place and a soft contact lens is placed over the eye as in PRK. The epithelial cells, which were partly devitalized by the weak alcohol solution, are laid over the treatment area and may serve as a facilitator of new epithelium healing underneath. The alcohol-devitalized epithelium falls off the eye, similar to a scab, in 5-10 days. These devitalized epithelial cells do not become the new surface of the eye, but simply serve as a protective agent in addition to the contact lens to facilitate comfort and healing of the new underlying epithelium. Alcohol treatment of the epithelium results in a severe amount of epithelial cell loss, a fact that may render the epithelial disk not usable, due to the reduced durability and adhesion on to the cornea.

Thus, there is a need for an automated corneal epithelium separator that addresses the above problems by separating the epithelial layer as a whole in a mechanical way, not chemical.

BRIEF SUMMARY

To help correct an imperfect vision of a patient's eye, an automated mechanical device separates the epithelial layer from the cornea of a patient's eye from the cornea. After the epithelial layer is separated from the cornea, a

laser is used to help correct imperfections in the cornea. Thereafter, the epithelial layer is placed back on the cornea to reduce the visual rehabilitation period and reduce postoperative pain.

In one aspect, the device includes a separator such as a plate, wire or dull blade. The device can preserve a separated epithelial layer as a disk without rupturing the disk and without substantial epithelial cell loss. The epithelial layer is separated from the cornea without cutting the cornea.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a diagram showing a side view of an eye and a cornea separator with a separator located in a first position according to the preferred embodiments.

Fig. 2 is a diagram showing a top view of the eye and the separator located in a first position according to the preferred embodiments.

Fig. 3 is a diagram showing a side view of the eye and the separator located in a second position according to the preferred embodiments.

Fig. 4 is a diagram showing a top view of the eye and the separator located in a second position according to the preferred embodiments.

Fig. 5 is a diagram showing a side view of the eye and the separator located in a third position according to the preferred embodiments.

Fig. 6 is a diagram showing a top view of the eye and the separator located in a third position according to the preferred embodiments.

Fig. 7 is a diagram showing a side view of the eye and the separator located in a fourth position according to the preferred embodiments.

Fig. 8 is a diagram showing a top view of the eye and the separator located in a fourth position according to the preferred embodiments.

Fig. 9 is a diagram showing a top view of the eye and the separator located in a fifth position according to the preferred embodiments, the separator is retracted after epithelial separation.

Fig. 10 is a diagram showing a top view of the eye with the separator removed.

Fig. 11 is a diagram showing a top view of the eye after ablations is performed with a laser.

Fig. 12 is a diagram showing a top view of the eye with the epithelium replaced on the eye.

Fig. 13. is a diagram showing a top view of the eye with the epithelium smoothly stretched into place.

Fig. 14 is a diagram showing a side view of the eye and the cornea separator device including a rotating drum.

Fig. 15 is a diagram showing a front view of the eye and the cornea separator device including the rotating drum.

Fig. 16 is a diagram showing a top view of the eye and the cornea separator device including the rotating drum.

Fig. 17 is a diagram showing a drum according to one embodiment.

Fig. 18 is a diagram showing a drum according to another embodiment.

DETAILED DESCRIPTION

To help correct an imperfect vision of a patient's eye, an automated mechanical device separates the epithelial layer from the cornea of a patient's eye from the cornea. A separator, such as a plate, wire or dull blade is used to separate the epithelial layer of the cornea from the basal membrane. In this way, the automated mechanical device can preserve the separated epithelial layer as a disk without rupturing the disk and without substantial epithelial cell loss, less than 5-10% loss, to ensure viability and stability of the epithelial disk after replacement on the surface of the cornea. After the epithelial layer is separated from the cornea, a laser is used to help correct imperfections in the cornea. Thereafter, the epithelial layer is placed back on the cornea to aid in the healing process of the eye.

Fig. 1 is a diagram showing a side view of an eye 10 of a patient and a cornea separator device 12. The cornea separator device 12 includes a separator 14, shown here in a first position located away from the eye 10. The separator 14 includes a device that can scrape the epithelium from the cornea such as a plate, a wire or a knife with a dull edge. The separator 14

removes an epithelium layer 16 located above a corneal surface 18 of the eye 10. The separator 14 is not sharp enough to excise corneal tissue during operation of the cornea separator device 12.

Referring also to Fig. 2, the cornea separator device 12 includes a ring 20 that sits on the eye 10 with its plane parallel to a limbus of the eye. The ring 20 includes an internal diameter 22 ranging from about 10 to about 12 mm and external diameter 24 from about 13 to about 16 mm and including a groove 26 (best seen in Fig. 15). The groove 26 is dimensioned wider than the internal diameter 22. A separator support 28 fits in the groove 26 to carry the separator 14 on a determined travel.

An oscillation device 30 provides motion and vibration to the separator 14. The oscillation device 30 can oscillate the separator 14 either transversely or longitudinally with frequency ranging from about 10Hz to about 10KHz. Electromagnetic or piezoelectric forces on the separator 14 can provide the oscillation, or external rotating or vibrating wires can provide the oscillation. To maintain the ring 20 on the eye 10, for example during oscillation, the ring 20 can include a circumferential groove 32 positioned on a side of the eye 10. Suction can be applied to the circumferential groove 32 to ensure stable mounting of the ring 20 to the eye 10.

Figs. 3 and 4 are diagrams showing a side and a top view, respectively, of the eye 10 and the separator 14 located in a second position with respect to the eye. As the separator 14 travels to contact the eye 10, the corneal surface 18 is flattened. To accommodate the travel of the separator 14, the separator support 28 freely slides in the groove 26, for example, when driven by the oscillation device 30.

Figs. 5 and 6 are diagrams showing a side and a top view of the eye 10 and the separator 14 located in a third position. As the separator 14 travels along the cornea 10, the epithelium layer 16 is separated from the cornea. The separator 14 separates the epithelium layer 16 without cutting the cornea 18.

Figs. 7 and 8 are diagrams showing a side and a top view of the eye 10 and the separator 14 located in a fourth position. In one embodiment, the

travel of the separator 14 is controlled to produce an epithelial disk 34 hinged at an edge 36 of the epithelial disk 34. In another embodiment the epithelial disk 34 is completely detached for the corneal surface 18, for example, as described below.

Fig. 9 is a diagram showing a top view of the eye 10 and the separator 14 located in a retracted position after the epithelial disk 34 as been formed. After the separator 14 is retracted, suction to the circumferential groove 32 is turned off and the cornea separator device 12 is removed from the eye 10. Referring also to Fig. 10, after the cornea separator device 12 is removed, a deepithelialized area 38 is exposed that corresponds to a shape and size of the area that the separator 14 contacted during travel.

Fig. 11 shows a top view of the eye 10 after laser ablation is performed. The laser ablation forms an irradiated area 40 on the eye 10. Referring to Fig. 12, thereafter, the epithelium disk 34 is replaced on the corneal surface 18 of the eye 10 to aid in the healing process. Referring to Fig. 13, once replaced on the corneal surface 18, the epithelium disk 34 is preferably smoothly stretched into place.

Fig. 14 is a diagram showing a side view of the eye 10 and the cornea separator device 12 including rotating drum 42. To rotate the drum 42, the cornea separator device 12 may include a rotating gear 44. The gear 44 could also be used to provide movement to the separator support 28. Referring also to Fig. 15 and 16, front and top views, respectively, of the cornea separator device 12, the rotating gears 44 could be bilaterally placed on the separator support 28. The oscillating device 30 can provide for rotation of the gears 44 and the gears 44 can travel on rails, for example toothed rails, which run parallel to the groove 26.

Since a typical thickness of an epithelial disk 36 includes about 50 microns, to preserve an epithelial disk 36, a separated epithelial disk 36 is rolled onto the drum 42. The drum 42 can include a diameter ranging from about 3 to about 9 mm and a length of about 12 mm. Referring also to Fig. 17, in one embodiment, to maintain integrity of the epithelial disk 36, the drum 42 can be coated with a hydrating and/or a conditioning substrate. The

hydrating and/or conditioning substrate can include, for example, HEMA contact lenses, tissue culture media, silicone and biocompatible hydrogels. The hydrating and/or conditioning substrate can be removed from the drum after the epithelial disk 36 attaches on to the drum. Thereafter, the epithelial disk 36 can be removed from the drum 46 and replaced on the corneal surface 16, as described above.

Fig. 18 shows another embodiment of the drum 42 includes apertures 46 and a connector 48 that connects to a suction source (not shown). By applying suction to the apertures 46 of the drum 42, the epithelial disk 36 can be rolled onto the drum 42. Thereafter, the epithelial disk 36 can be removed from the drum 46 and replaced on the corneal surface 16, as described above.

While the invention has been described above by reference to various embodiments, it will be understood that many changes and modifications can be made without departing from the scope of the invention. It is therefore intended that the foregoing detailed description be understood as an illustration of the presently preferred embodiments of the invention, and not as a definition of the invention. It is only the following claims, including all equivalents, which are intended to define the scope of this invention.